9/19/01

PATENT

Attorney Docket No. DHI-03864

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: James L. Brown
Serial No.: 09/539,735 Group No.: 1644
Filed: 03/30/00 Examiner: P. Nolan
Entitled: **DIAGNOSIS OF AUTOIMMUNE DISEASE**

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231, on **September 4, 2001**.

By: James R. Davenport

Sir:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the International Search Report for the related International Application No. PCT/US01/10184:

- U.S. Patent No. 5,814,461 to Bergmann *et al.*, (9/29/98). Bergmann *et al.*, disclose methods for detecting anti-thyroid stimulating hormone receptor (TSHR) autoantibodies in a fluid sample. These methods involve the use of a competitive sandwich assay, wherein the TSHR autoantibodies in a test sample bind to soluble TSHR, this inhibits the binding of soluble thyroid stimulating hormone (TSH). The TSH in solution is then free to bind to an immobilized TSH-specific antibody. TSH bound to the immobilized antibody can be detected either directly by prior incorporation of a label onto the soluble TSH

or indirectly with the use of a labeled, soluble TSH-specific antibody. Thus, the methods of Bergman indirectly quantitate TSHR-specific autoantibodies by measuring TSH. Unlike the claimed invention, Bergmann *et al.* do not disclose providing cultured cells selected from FRTL-5, CHO-R and CHO-RLuc cells, wherein said cells are contained within a testing means, and polyethylene glycol; and

- Morgenthaler *et al.*, "Application of a bioassay with CHO cells for the routine detection of stimulating and blocking autoantibodies to the TSH-receptor," *Horm Metab Res* 30:162-168 [1998]. Morgenthaler *et al.* disclose methods for detecting anti-TSHR autoantibodies through measuring the quantity of cAMP produced by CHO-R cells. In contrast to the claimed invention, Morgenthaler *et al.* do not disclose providing cultured cells selected from FRTL-5, and CHO-RLuc cells. Moreover, in preferred embodiments the methods of Morgenthaler *et al.* are used to test unfractionated serum for anti-TSHR autoantibodies and unfractionated serum does not contain polyethylene glycol.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: September 4, 2001

Kamrin T. MacKnight
Registration No. 38,230

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
415/904-6500